

## REMARKS

Claims 1-36 are pending in the application prior to entry of this amendment. Claims 1, 8, 9, 14, 18, 19, 25, 28, 31-33, and 35 are being amended; Claims 3, 16 and 30 are canceled without prejudice; and Claims 37-46 are added.

In the April 11, 2003 Office Action, the Examiner objected to Claim 28. Claim 28 has been amended as suggested by the Examiner.

The Examiner also rejected Claims 1-13, 19 and 20 under 35 USC § 112 as being indefinite. In particular, the Examiner noted claims 1, 8, 9, 19 and 20 were written in improper method claim format. Appropriate correction has been made to these claims. Accordingly, Applicant submits that this rejection has been obviated.

The Examiner rejected Claims 1-4, 6, 7, 13-16, 18, 20, 24-27, 29, 30, 32 and 36 under 35 USC §102(b) as being anticipated by U.S. Patent 6,129,675 to Jay. The Examiner also rejected Claims 1-9, 13-20, 24-32 and 36 under 35 USC §102(b) as being anticipated by U.S. Patent 5,273,036 to Kronberg et al. The noted claims include three Independent Claims (Claims 1, 14 and 25), each of which was rejected by both cited references. As set forth below, all the claims are believed to be allowable as presented and therefore, these rejections are respectfully traversed. Independent Claims 1 and 14 are first discussed below.

Independent Claim 1 is directed to a method for monitoring a physiological parameter of a patient. The method includes the steps of obtaining a pleth signal that includes at least a first respiratory component and a second Mayer wave component that is associated with a patient's autonomic nervous system. This pleth signal is processed to distinguish effects associated with the respiratory components from an effects associated with the Mayer wave components. A distinguished effect is utilized for monitoring a physiological parameter. For example, an effect

associated with the Mayer wave may be utilized to monitor, inter alia, hypertension, ventricular tachycardia and/or coronary artery disease. Alternatively, an effect associated with the patient's respiratory system may be utilized to monitor, for example, heart rate and/or pulse rate. The difficulty associated with monitoring physiological parameters based on an effect associated with a respiration component and/or Mayer wave component of a pleth signal is that these components can occur within overlapping frequency ranges. In this regard, the method of claim 1 allows for isolating these components such that an effect associated with these components may be identified for use in subsequent monitoring procedures. That is, effects of one component (i.e., the Mayer wave or the respiration) are isolated such that a particular physiological parameter can be more readily monitored.

Jay fails to recognize the existence of the Mayer wave or the desirability of isolating the Mayer wave components from respiratory system components in order to provide improved physiological monitoring. As presented, Jay provides a device and method for measuring pulsus paradoxus. As defined by Jay, the medical term pulsus paradoxus refers to a quantifiable exaggerated decrease in arterial blood pressure during inspiration. See Column 1 lines 19-22. To generate a pulsus paradoxus signal, Jay extracts from a pleth signal a first frequency component related to respiration and a second frequency component associated with pulse. See Column 3 lines 50-61. Jay correlates these components to generate the pulsus paradoxus signal. See Column 4 lines 61-68. Jay fails to recognize that the first frequency component related to respiration may overlap with a frequency component related to the Mayer wave. Accordingly, Jay fails to provide a method for distinguishing between effects associated with the Mayer wave and effects associated with the respiratory component. Applicant submits that Jay fails to disclose or suggest the claimed subject matter of Claim 1 and respectfully requests this rejection be withdrawn.

Kronberg fails to recognize the existence of the Mayer wave and/or the desirability of isolating components associated with the Mayer wave in a pleth signal from respiratory components for monitoring purposes. As presented, Kronberg provides a method for monitoring a patient's respiration utilizing a pulse oximeter. However, Kronberg fails to recognize that Mayer wave components within the pleth signal may overlap with the respiratory components and thereby effect the accurate monitoring of such respiration. Accordingly, Applicant submits that the Kronberg fails to disclose or suggest the claimed subject matter and respectfully requests this rejection be withdrawn.

Independent claim 14 provides a method for monitoring a patient's respiration based on a base-line portion of a pleth signal. In this regard, an optical signal is transmitted relative to a patient such that the signal interacts with the blood of the patient. A detector system detects the transmitted optical signal and provides a pleth signal indicative of the detected optical signal, which includes at least a first respiratory component and a second Mayer wave component associated with the patient's autonomic nervous system. First, the pleth signal is processed to isolate a pulsatile pleth signal and a baseline signal. Secondly, the baseline signal is processed to distinguish an effect associated with the first component from effects associated with the second component. Effects associated with the Mayer wave may be distinguished from effects associated with the respiratory wave within the baseline pleth signal. Accordingly, the distinguish effect may be utilized to monitor a patient's breathing. The method of claim 14 recognizes that the baseline signal includes the respiratory component(s) and the Mayer wave component. Furthermore, the method of Claim 14 recognizes that these individual components may be more easily distinguished within the baseline signal than within the AC pleth signal or a combined pleth signal. Accordingly, enhanced monitoring of a patient's breathing may be provided.

As noted above, Jay fails to recognize the existence of the Mayer wave or the desirability of isolating the Mayer wave components from respiratory system components in order to provide improved physiological monitoring. Furthermore, Jay fails to disclose or suggest the isolation of a baseline portion of a pleth signal for use in monitoring a patient's breathing. Accordingly, Jay fails to disclose the subject matter of Claim 14 and Applicant respectfully requests that this rejection be withdrawn.

Kronberg fails to recognize the existence of the Mayer wave. Accordingly, Kronberg fails to recognize, inter alia, the use of a baseline portion of pleth signal to isolate respiratory components and Mayer wave components that may be utilized to monitor respiration. Accordingly, Applicant submits that the Kronberg fails to disclose or suggest the subject matter claimed in Claim 14 and respectfully requests this rejection be withdrawn.

Independent Claim 25 has been amended to generally include the content of Claim 33. Claim 33 previously depended from Claim 25. The Examiner indicated that Claim 33 would be allowable if presented in independent form. Therefore, Applicant submits that Claim 25 and all claims depending therefrom are allowable.

New Independent Claim 37 corresponds to Claim 1 rewritten to include the limitations of dependent Claim 10. As written, new Claim 37 does not recite the limitations set forth in previous dependent Claim 6, from which Claim 10 depended. Furthermore, applicant has removed the term phase from dependent claim 10. The term phase has been retained in new dependent claim 40. However, applicant respectfully submits that New claim 37 is allowable as presented.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation

would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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